

# *Prelude Computer Solutions, Inc.*

**DocuKnowledge Suite  
Presentation for the FDA  
August 9, 2001**



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# *Objectives*

- Introduce Prelude Computer Solutions, Inc.
- Get FDA feedback on Prelude's DocuKnowledge Suite
- Recognition on Public Docket





# *Package Contents*

- Presentation
- Part 11 Response
- Validation Approach
- Screen Shots





# *Prelude Computer Solutions, Inc.*

- Specializing in regulated solutions for the pharmaceutical and life sciences.
- Full service integrator
- Concentrating on Document Management and Publishing of documents for the FDA
- Founded in 1989

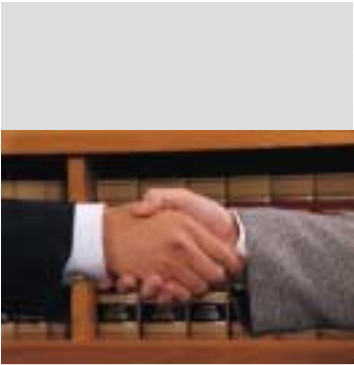




# *Agenda*

- The Business Challenge- The DocuKnowledge Suite and why it came to be
  - Prelude Design Requirements
  - Business Goals
  - Testing Process
- DocuKnowledge Suite- what is it
  - Features and Benefits
- DocuKnowledge Demonstration
- Part 11 Test Results





## *The Business Challenge*

- Results of a Business Analysis for large OTC Consumer Health organization
- Build an affordable, turn-key system for Electronic Submissions based on industry standard software, that is Part 11 compliant and follows the Guidance for Industry Documents.





# *Target Market*

- Who our product appeals to:
  - Companies without large staffs
  - OTC
  - Small Pharma
  - Medical Device
  - Biotech
  - Rx companies without systems or augmenting existing systems





# *Prelude Design Requirements*

- System must meet requirements of FDA Part 11
- System must produce .pdf files formatted and organized as per FDA:
  - Guidance for Industry Documents
- Automate as much as possible to make it easier for users and reduce potential errors







# *Prelude Design Requirements*

- Out-of-the-box, lower cost solution for electronic submissions
- Software had to be
  - Name brand software platforms
  - Web based document management
  - Scalable- entry level to enterprise
  - Secure





# *Prelude Design Requirements*

- IBM/Lotus Domino.Doc document management
  - Global, multi language support
  - Several million licenses sold
  - Corporate standard for mail
- CDC Solutions EZ*subs* Team publishing





# *Prelude Design Requirements*

- Audit Trails & Version Control
  - Computer Generated
  - Time and Date Stamped
  - Operator Identified
  - Anytime Record is Created, Modified, or Deleted
  - Modifications Can Not Obscure Previous Information
- Enforce Review and/or Approval





# *Prelude Design Requirements*

- Integrated
  - Word templates must work with the publishing system to create TOC's
  - Word templates need to include metadata in properties field when converted to .pdf as per Guidance Documents





# *Prelude Design Requirements*

- Documents must be automatically extracted from EDMS into file system to create an NDA
- Extraction program needs to create the directory structure and be flexible enough to handle diverse submission types
- Publishing system should have initial TOC's automatically created





# *Prelude Design Requirements*

- Extraction program able to be used as a Project Management tool to determine the status of a submission.
- Replaces manual tracking sheets





## *Prelude Business Goals*

- Provide a solution that can be used by a broader group of companies
- Provide faster turnaround and easier implementation
- Reduce manual errors and enforce compliance by automating as much as possible
- Only non-Documentum based alternative that fully automates integration between document management and publishing (As of presentation date, we are the only one)





# *Process of Testing*

- Using our Requirements Based on Part 11 and Guidance Documents
- Evaluated Domino.Doc and EZsubs Team
- Tested Domino.Doc for Part 11 suitability
  - Renowned security, global support
  - Tested specific features for audit trail, versioning, change/deletion, security
- Evaluated EZsubs for integration with Domino.Doc
  - EZsubs had already been used for submissions



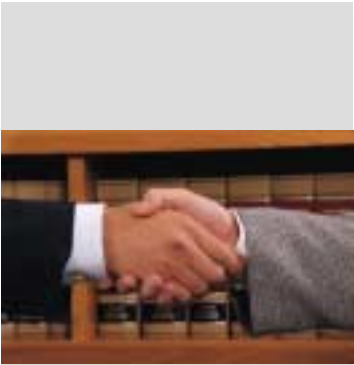




## *Our Testing Results*

- Documented our testing
- Created list of enhancements to Domino.Doc
- Created specs for Domino.Doc/EZsubs integration module
- Implemented enhancements, documented, validated
- Created validation kits for use by customers



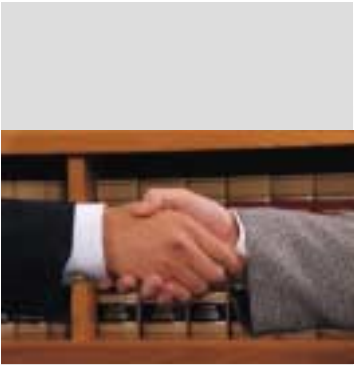


# *DocuKnowledge Suite*

**A Full Service Integrated Solution  
for Document Management and  
Publishing**



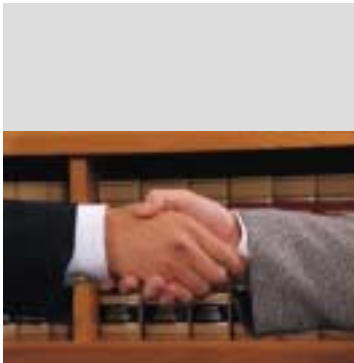
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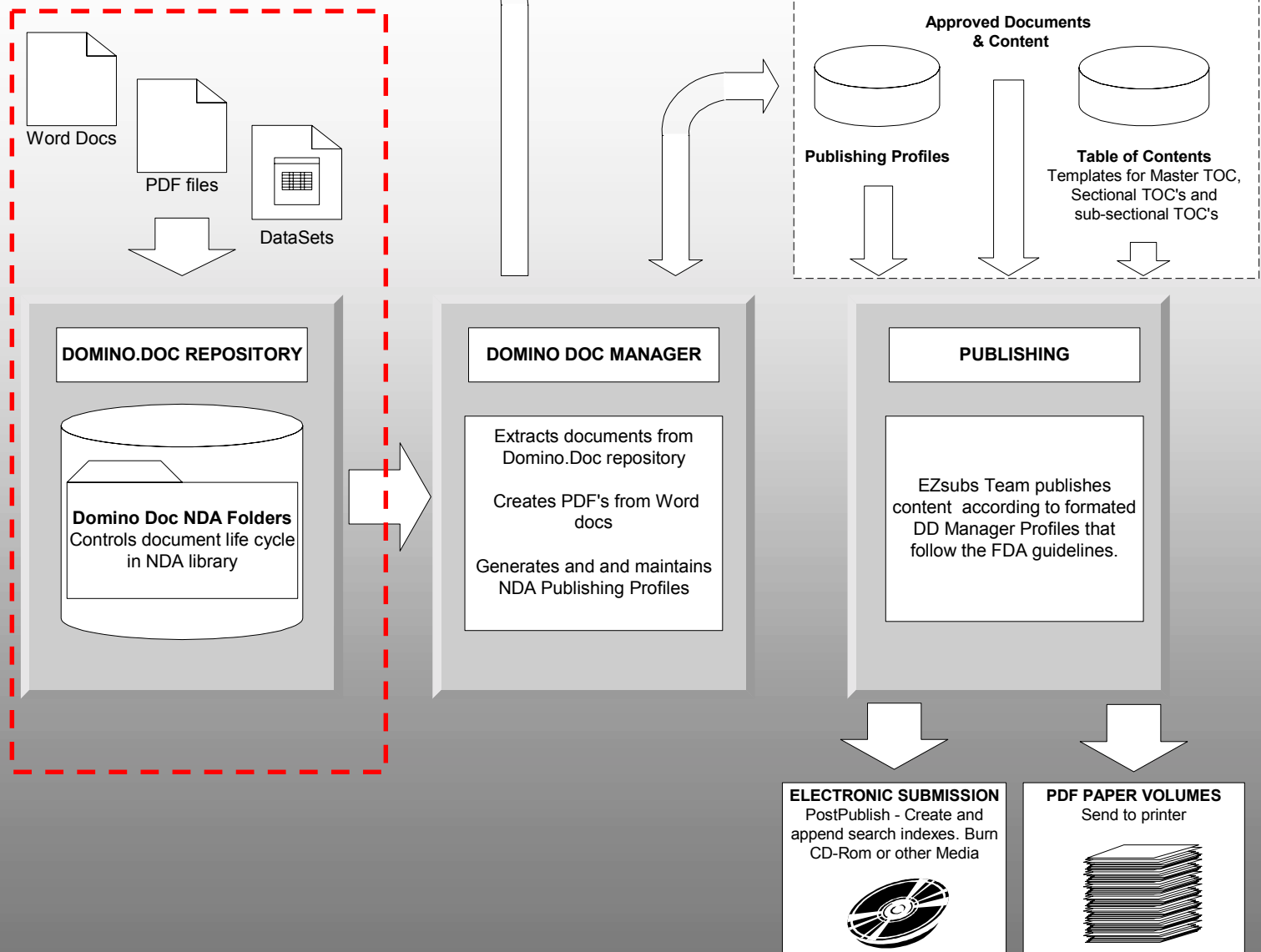
# *DocuKnowledge Suite*

- Consulting and Integration Services
  - DocuPartner
- Document Management Products
  - DocuLibrary, DocuSub, DocuLabel, DocuSOP, DocuPromo, DocuStyle
- DDManager
  - Extraction and Project Management
- Publishing Products
  - DocuPub
- Validation Products and Services

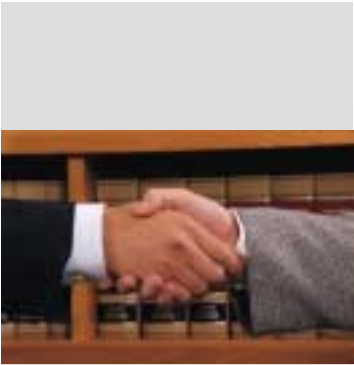




# Process Flow

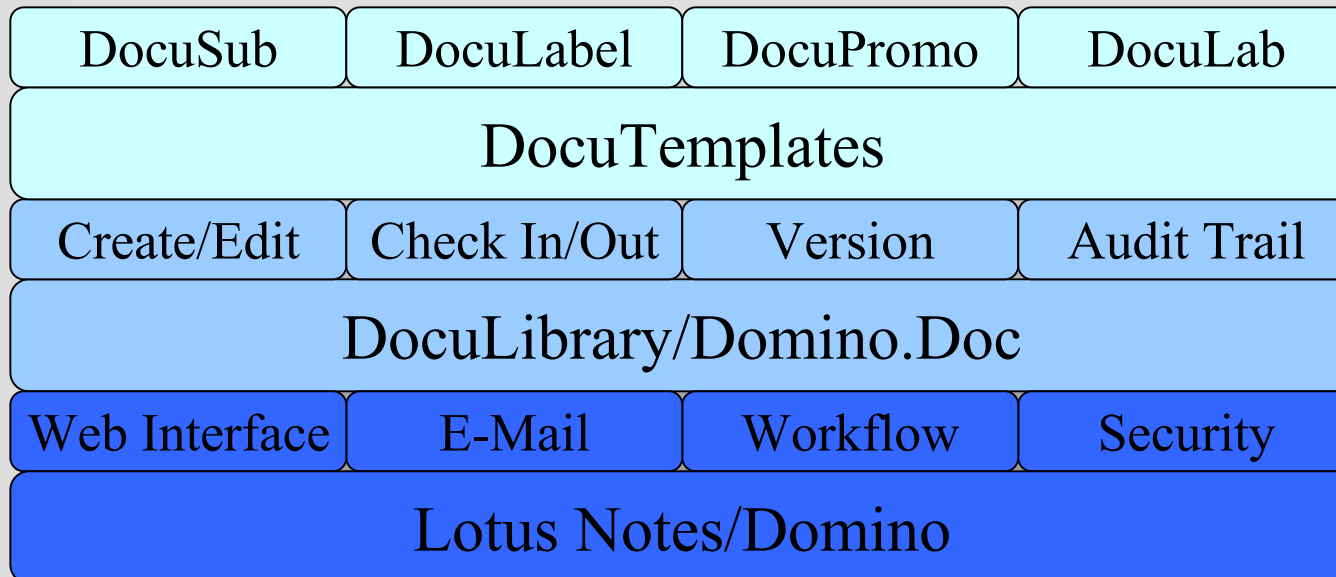


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# *DocuKnowledge Suite*

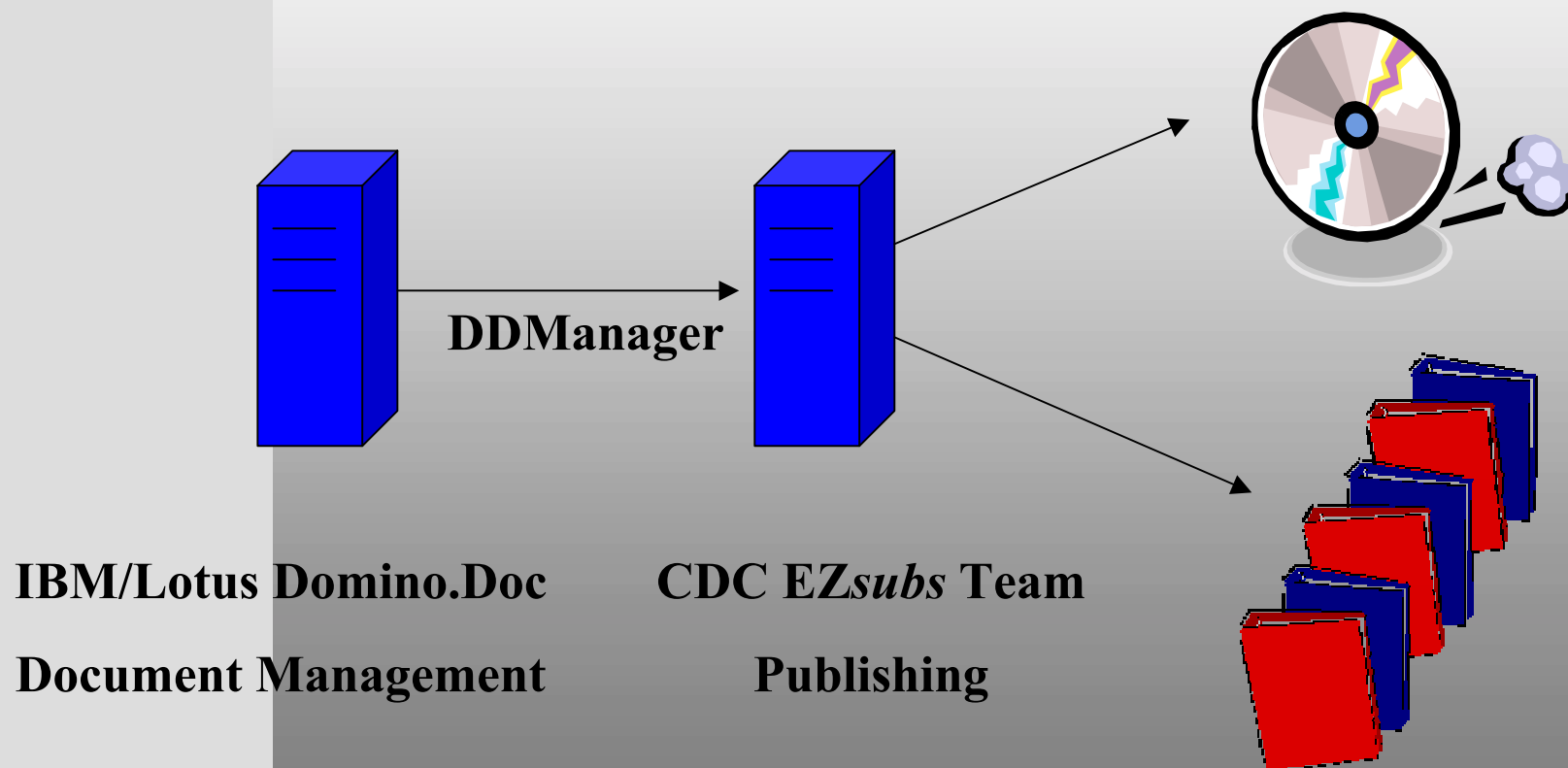
DocuLibrary- Document Management Architecture



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# *DocuSub Package for Electronic Submissions*



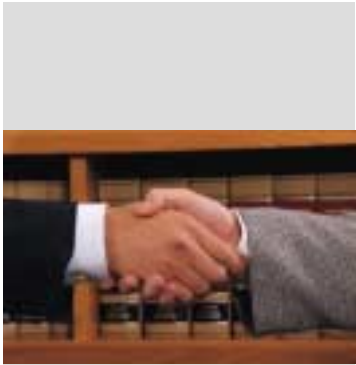
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# *DocuSub Package for Electronic Submissions*

- Completely integrated system for Electronic Submissions including:
  - Document Management
  - Publishing
  - Integration
  - Business Analysis- Requirements, Workflow, Process
  - Validation



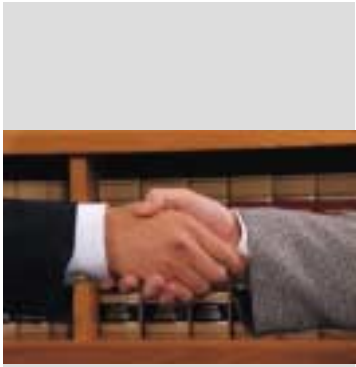


# *DocuSub Package for Electronic Submissions*

- Document Management
  - DocuLibrary- Domino.Doc
  - Part 11 Extensions
  - Specialized Templates for
    - DocuTemplates -Document Management
    - DocuStyle- Word
    - DocuTest- Validation
- DDManager
  - Project Management
  - Document Extraction and Directory Creation
  - PDF Rendering



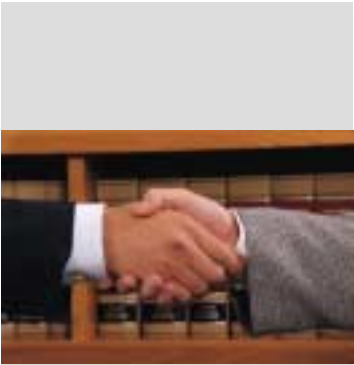




# *DocuSub Package for Electronic Submissions*

- Publishing
  - DocuPub- EZsubs Team
  - Specialized Templates
    - NDA Template
- DocuPartner
  - Business Analysis
    - Requirements Document
    - Workflow
    - Project Planning
- Validation
  - DocuTest- Boiler Plate Kits
  - Services





# *DocuTemplate Components*





# *DocuTemplates*

- Additional Templates for Domino.Doc
  - Label Tracking and Approval Templates
  - Promotional Material Approval Templates
  - Lab Notebook Templates
  - SOP's





# *Advantages to Domino.Doc*

- Web Enabled
  - Ease of use, training, IT support
  - Web-Enabled Review\*
  - Web-Enabled Approval\*
- Infrastructure Friendly
  - Works with Common Mail Systems

\* Both integrated into your current mail system



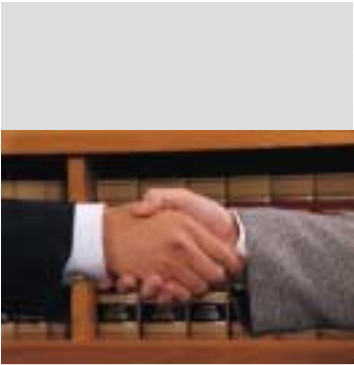
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# *Advantages to Domino.Doc*

- Easily Configured
- Departmental Administration
  - Leverage and train existing staff instead of hiring more people
- Attributes Migrate for Upgrades without Programming Changes
- Personalized Workspace
  - Increase Productivity
  - Increase Ease of Use

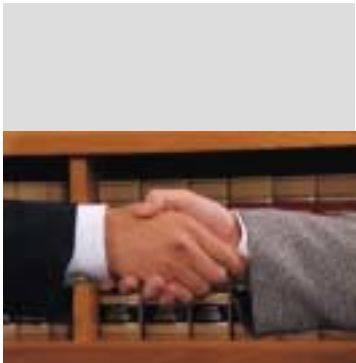




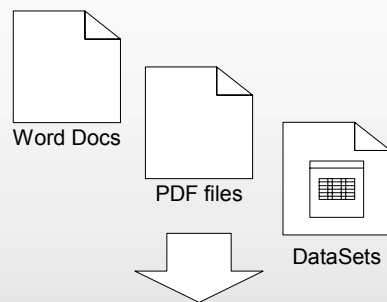
# *Advantages to Domino.Doc*

- Personal Workspace/Home Page Contains
  - Checked Out Documents
    - Editors can see what they have checked out
  - Recently Edited
    - Editors see what they have recently been working on
  - Lifecycle View
    - Reviewers see only their own work
  - Favorites
    - Authors and Editors can bookmark their favorite pages

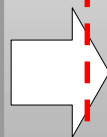
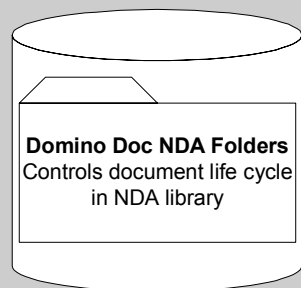




# Process Flow



## DOMINO.DOC REPOSITORY

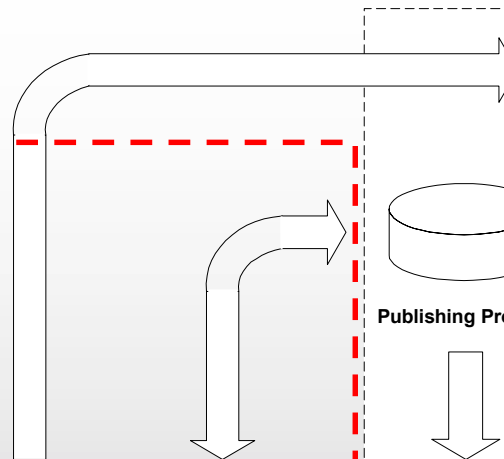


## DOMINO DOC MANAGER

Extracts documents from  
Domino.Doc repository

Creates PDF's from Word  
docs

Generates and maintains  
NDA Publishing Profiles



## Approved Documents & Content

## Publishing Profiles

**Table of Contents**  
Templates for Master TOC,  
Sectional TOC's and  
sub-sectional TOC's

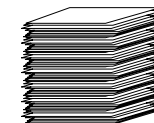
## PUBLISHING

EZsubs Team publishes  
content according to formatted  
DD Manager Profiles that  
follow the FDA guidelines.

**ELECTRONIC SUBMISSION**  
PostPublish - Create and  
append search indexes. Burn  
CD-Rom or other Media



**PDF PAPER VOLUMES**  
Send to printer



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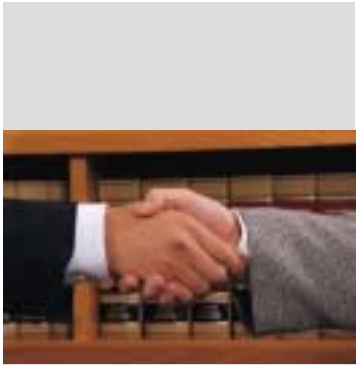


## *DDManager Functions*

- DDManager is the interface between Domino.Doc and Publishing
- Provides extraction of all content from Domino.Doc repository to the Publishing Server
- Creates and maintains EZsubs Publishing Profiles
- Provides document progress reports
  - Management of documents
  - Audit trail of activities
  - Log reports of DDManager activities







# *DDManager- Extraction Features*

- Extracts all or selected documents for publishing
- Creates the File structure required by FDA for submission media
- Updates all required document properties
  - Moves Domino.Doc Index card fields (metadata) to Word properties field
- Converts MS Word documents to PDF format

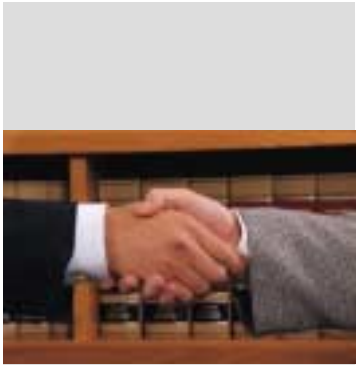




# *DDManager- Extraction Features*

- Audit Log- event activities and exceptions
  - Session ID, Task, User, Date, Time Stamp, successful completion
- Document Log- view log of documents extracted
- Submission specific extraction
  - NDA structure
  - PDF rendering
- Generic extraction
  - Native document format
  - User defined directories

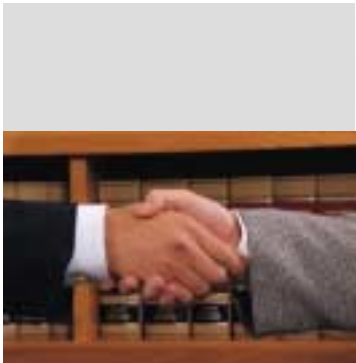




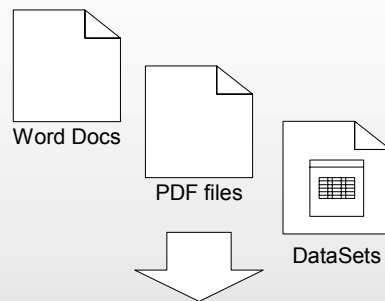
# *DDManager- Project Management Features*

- Status Reports
  - List of documents for the complete submission or sections of a submission with:
    - Status- Draft, Version, In Review, In Approval
    - Last person to modify
    - Date last modified

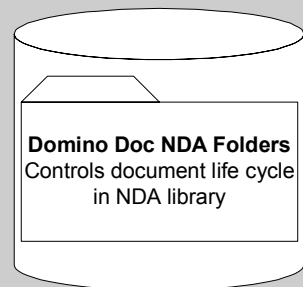




# Process Flow



## DOMINO.DOC REPOSITORY

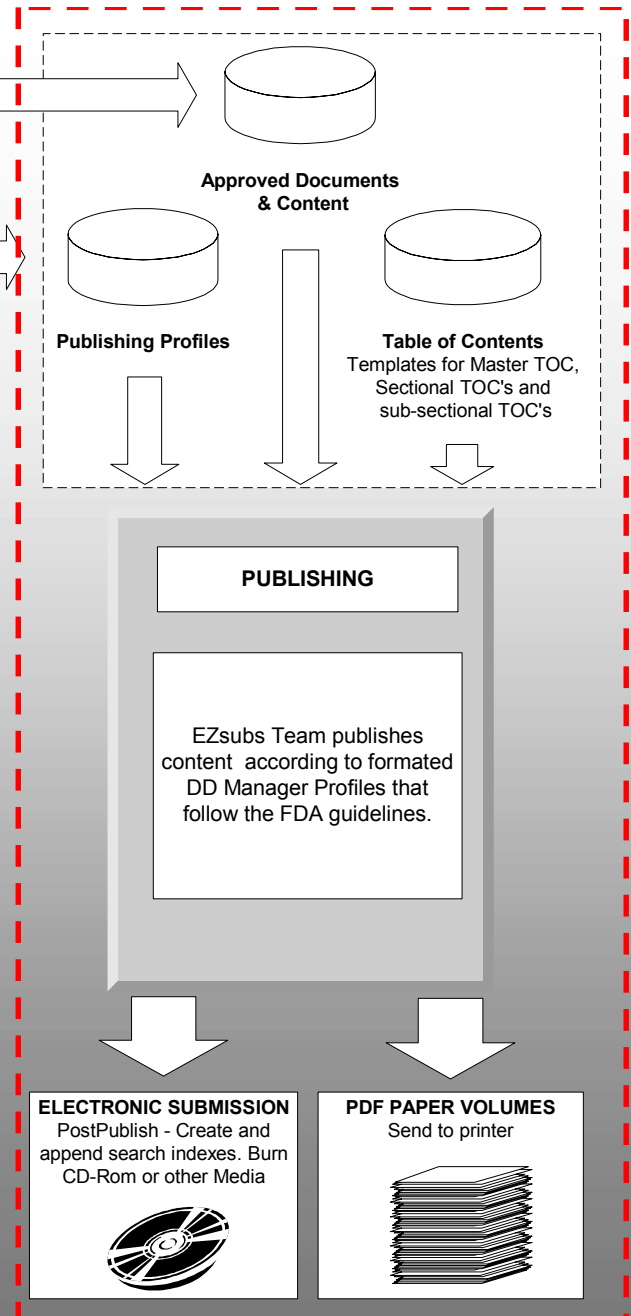
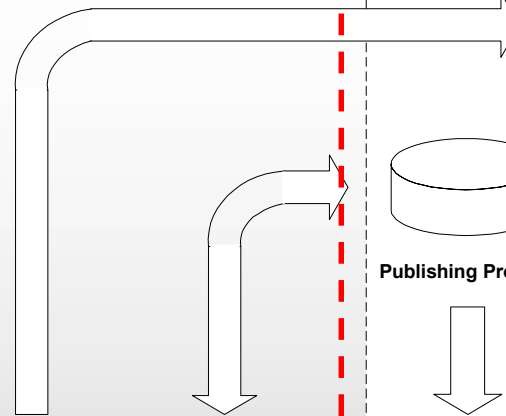


## DOMINO DOC MANAGER

Extracts documents from  
Domino.Doc repository

Creates PDF's from Word  
docs

Generates and maintains  
NDA Publishing Profiles



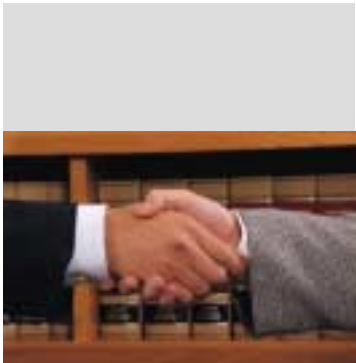
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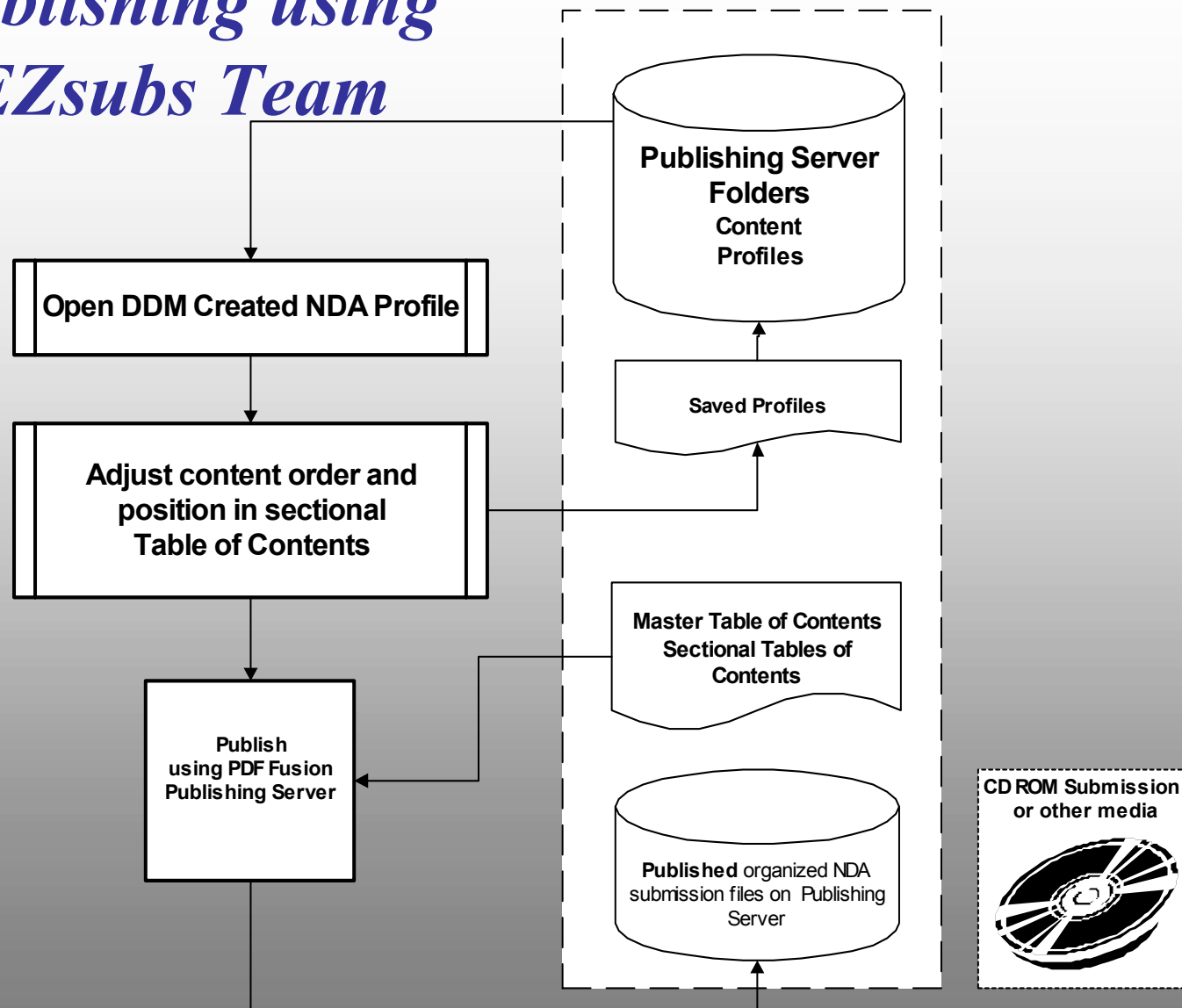
## *DocuPub- Publishing*

- CDC Solutions- *EZsubs* Team
- Team uses Publishing Profiles for adjusting content
- Initial publishing Profile organization is created and maintained by DDManager according to FDA Guidance for Industry guidelines
- *EZsubs* Team is a full featured desktop Publishing client
- CDC PDF Fusion is the publishing engine residing on a central publishing server

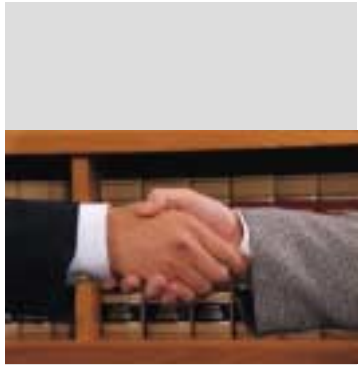




## ***Publishing using EZsubs Team***



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# *Validation Products & Services*

- DocuTest
  - Boiler Plate Model Kits for applications that include
    - Functional Requirements
    - System Design Spec
    - IQ, OQ, PQ
    - Test Scripts
- DocuPartner
  - Services for Assistance in
    - User Acceptance
    - Summary Reports



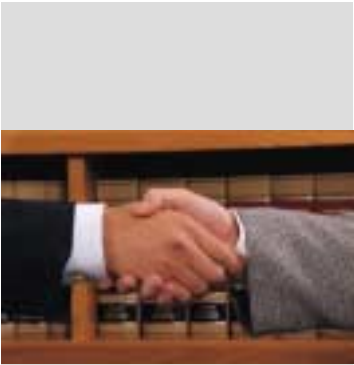


# *DocuKnowledge Suite*

- Part 11 Compliant
- Web Enabled
- Backed By Industry Leaders
- Affordable
- Expandable and Scalable
- Easy to Use and Configure
- Departmental Administration





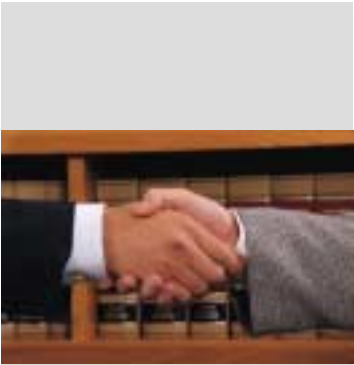


# *Demonstration*

## **DocuKnowledge Suite DocuSub- Electronic Submission System**



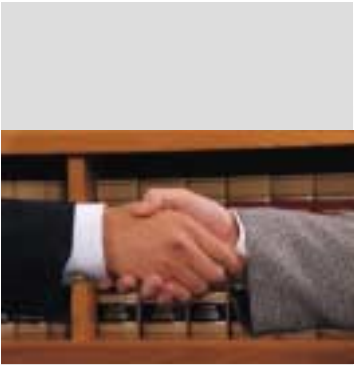
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## *Part 11 Results*



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## *Part 11 Results*

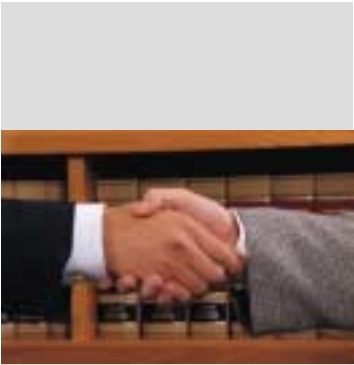
### 11.10 (b)

The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection review and copying by the agency.

#### DocuKnowledge Response-

All records, audit trails, and versions can be viewed, copied, and printed in human readable form.





## *Part 11 Results*

### 11.10 (c)

Protection of records to enable their accurate and ready retrieval throughout the records retention period.

#### DocuKnowledge Response-

The DocuKnowledge Suite provides customized templates (metadata) for retrieval of records. Industry standard search engines based upon IBM technology insure accurate retrieval.



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## *Part 11 Results*

11.10 (d)

Limiting systems access to authorized individuals.

DocuKnowledge Response-

Users must login using a unique login and password.



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## *Part 11 Results*

### 11.10 (e)

Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information.

DocuKnowledge Response-

Audit Trails, Version Control, and Security Agent



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## *Part 11 Results*

11.10 (f)

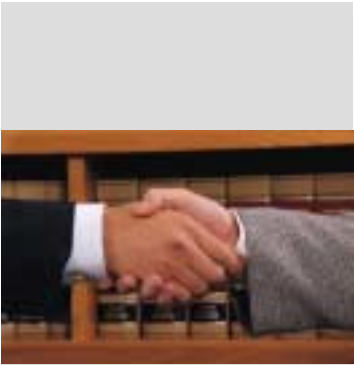
Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

DocuKnowledge Response-

The DocuKnowledge Suite only presents appropriate choices for selection.



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## *Part 11 Results*

### 11.10 (g)

Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation of computer system input or output device, alter a record, or perform the operation at hand.

#### DocuKnowledge Response-

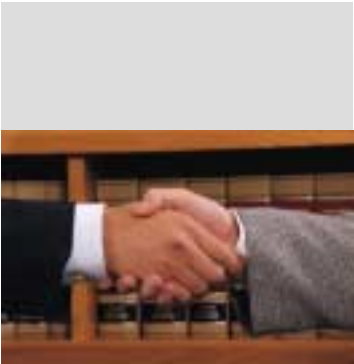
Users must login with unique user name and password.

Users can only see what they have the authority to read or edit. Currently comply to Part 11 and Guidance Documents for electronic signatures.



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## *Part 11 Results*

### 11.10 (i)

Determination that the persons who develop, maintain, or use electronic record/signature systems have the education, training, and experience to perform their assigned tasks.

#### DocuKnowledge Response-

Maintains CV's on all persons who develop, maintain, document, validate, train, and install the DocuKnowledge Suite products.





## *Part 11 Results*

11.10 (i) continued-

Prelude also requires all consultants to read the Part 11 and Guidance for Industry documents and complete review questions which are kept on file. Further training is done on SDLC policies and procedures. Technical training is also performed as new base product software is released, ie: document management and publishing.



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## *Part 11 Results*

### 11.10 (j)

The establishment of, and adherence to written policies that hold individuals accountable and responsible for actions initialed under their electronic signatures, in order to deter record and signature falsification.

DocuKnowledge Response-

Prelude maintains SDLC's and SOP' for our development. We assist pharmaceuticals in creating and maintaining SOP's.



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## *Part 11 Results*

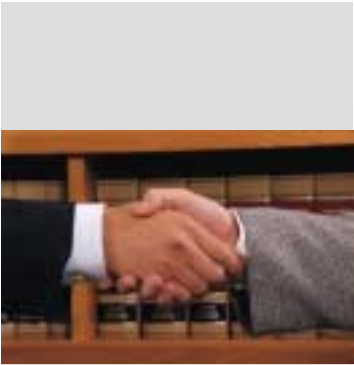
### 11.10 (k 1)

Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

#### DocuKnowledge Response-

Administration and user documentation is available both in paper and on-line.





## *Part 11 Results*

### 11.10 (k 2)

Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

#### DocuKnowledge Response-

Procedures for revision and change control are maintained in Prelude's SOPs.





## *Part 11 Results*

11.50

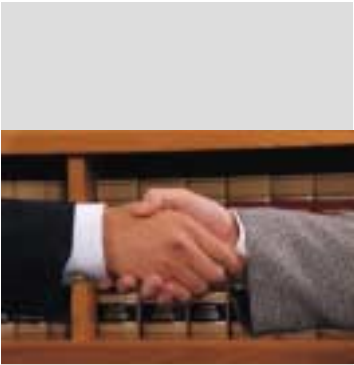
Signature Manifestations & Sub Part C- Electronic Signatures

DocuKnowledge Response-

Manifestation and meaning of all signatures is displayed on the profile attached to the specific document and version.



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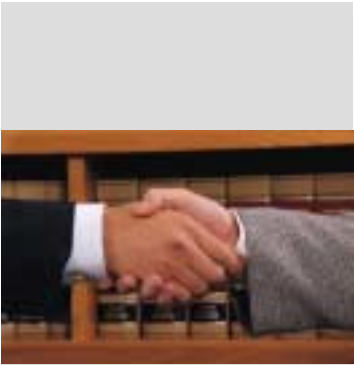


# *Appendix A*

## **Validation Approach**



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# *Validation Approach*

- Validation of Standard Product – Prelude Software Development
- Validation of Customer Solution







# *Prelude SDLC*

- System Development Methodology
  - Phased approach
  - Well-defined roles and responsibilities
  - Quality assurance
  - Specific deliverables for each phase
  - Produce documented evidence

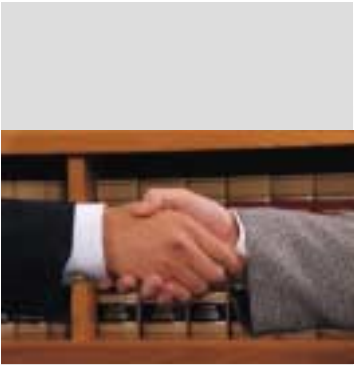




# *Prelude SDLC*

- Analysis
- Design
- Development - Unit Testing
- Pilot Implementation
- Integrated System Testing
- Qualification Testing & Deployment (Release)
- Change Control





# *Gap Analysis Results*

- Domino.Doc Customization
  - Met most requirements
  - Required customizations in the areas of deletion control and authentication enhancements
- CDC EZSubs Team Customization
  - Required standard templates to meet requirements outlined in guidance documents
- DDManager Module
  - Identified need for automated integration between document management and publishing

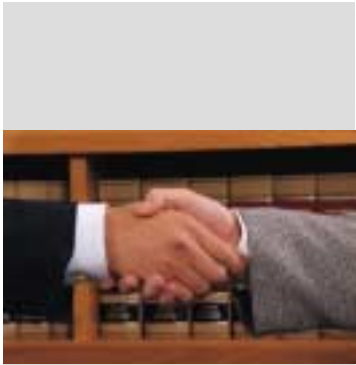




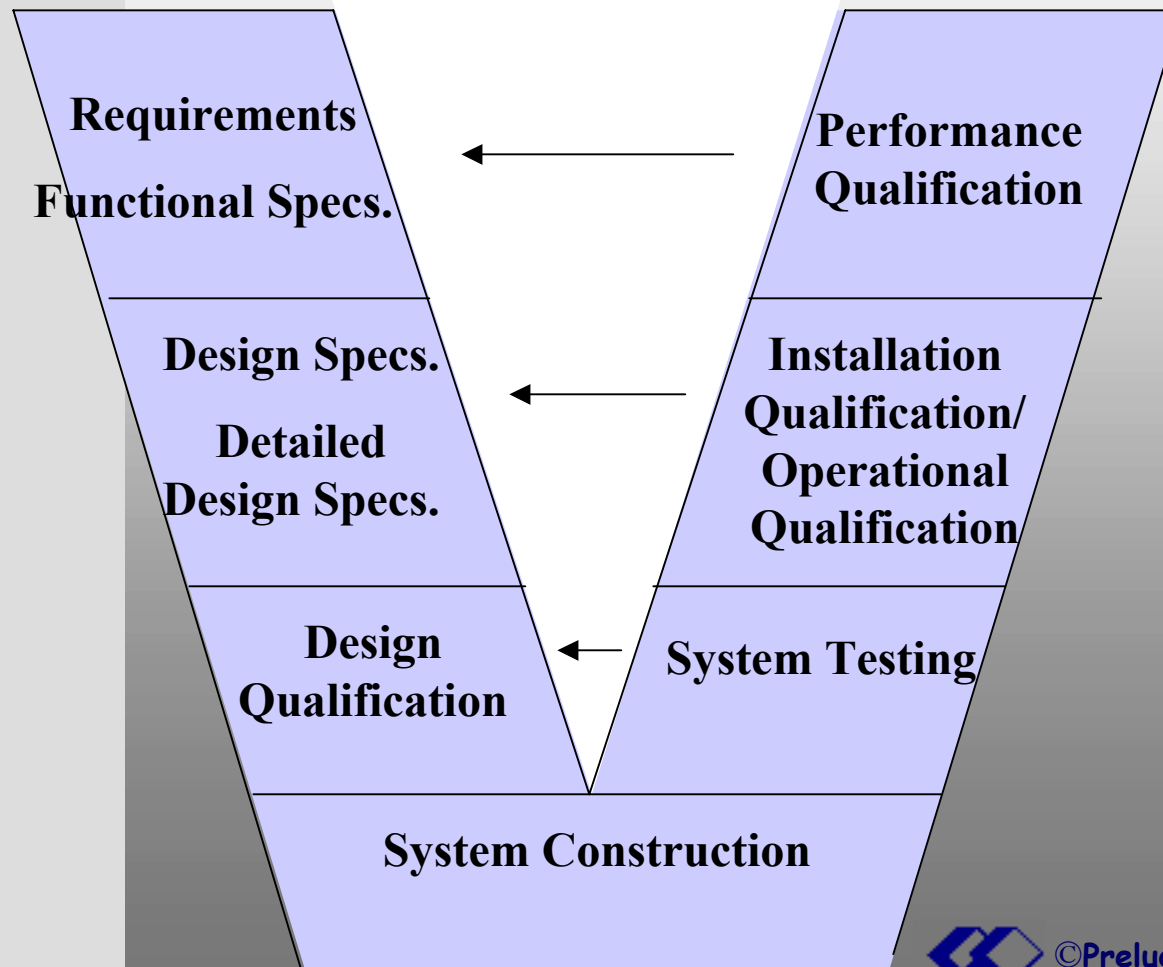
# *DocuSub Product*

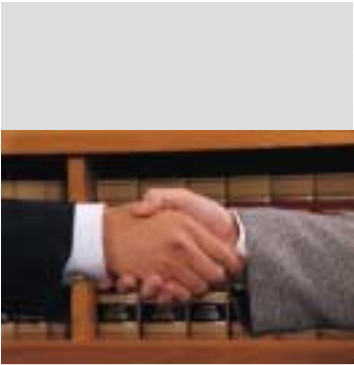
- Requirements:
  - FDA Guidance for Industry
  - 21 CFR Part 11
- Design & Development:
  - Domino.Doc was customized by utilizing Lotus Best Practices, ensuring an upgrade path for future versions
  - CDC EZSubs configuration of templates
  - DDManager was developed in Visual Basic adhering to a full development life cycle
- Testing:
  - Validated within the Prelude environment





# *Validation of Customer Solution*





## *OTC Consumer Health*

- Prelude validation team working with OTC QA
- Followed OTC Quality policies and standard validation templates
- Validated against NCH Part 11 interpretation
- Validation effort nearing completion





# *OTC Validation Deliverables*

- User Requirements Specification
- Functional Specification
- Functional Risk Assessment
- Validation Protocol (Plan)
- Design Specification for Document Management
- Design Specification for DDManager
- Design Specification for Ezsubs
- Test Plan
- Traceability Matrix





# *OTC Validation Deliverables*

- Test Script for Domino.Doc Server Installation Qualification (IQ)
- Test Script for Document Management Client Installation Qualification (IQ)
- Test Script for Document Management Operational Qualification (OQ)
- Test Script for Document Management Performance Qualification (PQ)
- Test Script for Publishing Server/Workstation Installation Qualification (IQ)







# *OTC Validation Deliverables*

- Test Script for Publishing Client Installation Qualification (IQ)
- Test Script for DDManager Installation Qualification (IQ)
- Test Script for DDManager Operational Qualification (OQ)
- Test Script for DDManager Performance Qualification (PQ)
- Test Script for EZsubs Team Operational Qualification (OQ)
- Test Script for EZsubs Team Performance Qualification (PQ)
- Validation Summary Report

